



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,123	08/28/2003	Denis Martin	484112.432	5510
500	7590	07/17/2009		
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC			EXAMINER	
701 FIFTH AVE			GRASEK, JENNIFER E	
SUITE 5400			ART UNIT	PAPER NUMBER
SEATTLE, WA 98104			1645	
		MAIL DATE	DELIVERY MODE	
		07/17/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/650,123	Applicant(s) MARTIN ET AL.
	Examiner Jennifer E. Graser	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on **4/22/09**.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) **2-5,7,11,12,17-20,24-27 and 34-45** is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) **2-5,7,11,12,17-20,24-27 and 34-45** is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted on 4/22/09 is made.

Claims 2-5, 7, 11, 12, 17-20, 24-27, and 34-45 are currently pending.

Applicants amendments to the claims and arguments have obviated the former 112, 1st enablement and written description rejections.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 2-5, 7, 11, 12, 14, 17-21, 23-27 and 34-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brodeur et al (WO 96/29412) in view of anyone of Ward et al (Microbial Pathogenesis. 1996. 21: 499-512), Idanpaan-Heikkila et al (Vaccine. 1995. 13(16): 1501-8), or Wright et al (Infection and Immunity, August 2002, 70(8): 4028-4034).

Brodeur et al teach an isolated outer membrane protein from *Neisseria meningitidis* which is 100% identical to the protein taught by Applicant's as SEQ ID NO: 2. Fragments of this protein are also taught as well as methods for producing it recombinantly. See top of page 6 and pages 18-19. It is taught that the protein may be used in prophylactic and diagnostic compositions and methods useful in the treatment,

Art Unit: 1645

prevention and diagnosis of *Neisseria meningitidis*. See abstract. Hybrid or chimeric proteins are also taught. Brodeur et al teach that this protein is highly conserved.

However, Brodeur et al do not specifically teach the use of a liposome, particularly one comprising a bacterial phospholipid selected from E.coli, N.meningitidis and N.lactamica with their polypeptide.

Ward et al teach that the incorporation of isolated *N.meningitidis* proteins into liposomes allows for the proteins to achieve optimal protein folding. It is taught that the use of liposomes replaced the use of LPS to promote native-like folding of the protein to an active conformation without the negative toxic effects associated with LPS. The use of adjuvants such as monophosphoryl lipid A or muramyl dipeptide along with the liposomes is specifically taught. However, it is taught that an effective bactericidal response was obtained with the purest preparation of protein incorporated into liposomes. Page 503 teaches how to incorporate the proteins into liposomes. Liposomes composed of phosphatidylcholine and cholesterol are taught. Page 508 teaches that the advantage of using liposomes is primarily the potential for folding of the protein in the liposomal membrane to a native-like conformation and the inherent immunoadjuvant activity of the liposome vesicles.

Idanpaan-Heikkila et al teach that when the outer membrane protein P1 from *N.meningitidis* was reconstituted with phosphatidylcholine into liposomes, native antigenic epitopes were formed. It is taught that the liposomes were reproducibly immunogenic at a low dose without any other adjuvant. The antibodies produced were both bactericidal and protective against infection in the infant rat model.

Wright et al teach the incorporation of the recombinant PorB outer membrane protein of *N.meningitidis* into liposomes for use as a vaccine. The liposome preparations proved to induce a much greater immune response than the PorB adsorbed to Al(OH)₃. It is further taught that reactivity with native protein was considerably enhanced by incorporation of the adjuvant monophosphoryl lipid A into the liposome. See abstract.

It would have been *prima facie* obvious to incorporate the isolated *N.meningitidis* protein taught by Brodeur et al (which is the same as the protein taught by Applicant's as SEQ ID NO:2) or its immunogenic fragments thereof, as well as fusion or chimerics of said protein, into liposomes because the prior art, as evidenced by Ward, Idanpaan-Heikkila et al, and Wright, extensively taught that incorporating isolated, denatured or recombinant *N.meningitidis* proteins into liposomes allows for the proteins to achieve optimal protein folding which allowed for native-like conformation. It is taught that the use of liposomes replaced the use of LPS to promote native-like folding of the protein to an active conformation without the negative toxic effects associated with LPS. One of ordinary skill in the art would have been motivated to incorporate the protein taught by Brodeur into liposomes because doing so not only allows for the protein to obtain native-like conformation, but also has the added benefit of the inherent immunoadjuvant activity of the liposome vesicles. The secondary references further teach that the liposomes may be used with or without a further adjuvant. The protein taught by Brodeur et al would inherently comprise an 'epitope-bearing portion'. The doses taught in instant claim 27 is consistent with what is taught by Brodeur et al. The prior art

teaches the identical polypeptide and the idea that using liposomes allows for the proteins to achieve optimal protein folding which allowed for native-like conformation as well as contain an additional adjuvant activity. Although the prior art references do not specifically recite that the liposome may be of bacterial cell origin, it was well known in the prior art that pharmaceutical compositions comprising liposomes could be constituted from phospholipids from bacterial cells, soybean or eggs and any one of these sources would work equally as well as functional equivalents. It is noted that the instant disclosure allows for the liposome to be synthesized or extracted from bacterial cells, soybeans or eggs. Phosphatidyl choline, phosphatidylserine, phosphatidylglycerol, glycerides, steroids, e.g., cholesterol are all suggested. The specific bacterial phospholipids which have been added to the claims would be expected to act functionally equivalent as these other sources of liposome and the addition of the specific source of the bacterial phospholipid to the claims does not impart novelty.

Response to Applicants' Arguments:

Applicants argue that Brodeur, nor the combination of reference, teach a NspaA protein, variant or fragment thereof formulated with a liposome comprising a bacterial phospholipid from E.coli, N.meningitidis and N.lactamica, in an immunogenic composition. They argue that the prior art as a whole must suggest the desirability of making the combination. This has been fully and carefully considered but is not deemed persuasive. First, the prior art as a whole does teach or suggest the desirability of formulating a Gram-negative bacterial protein with a liposome and the

references cited specifically teach the desirability of combining a *N.meningitidis* outer membrane protein with a liposome. The term 'immunogenic composition' is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the prior art references recited above, e.g., Ward, Idanpaan-Heikkila et al, and Wright, extensively teach that incorporating isolated, denatured or recombinant *N.meningitidis* proteins into liposomes allows for the proteins to achieve optimal protein folding which allowed for native-like conformation. It is taught that the use of liposomes replaced the use of LPS to promote native-like folding of the protein to an active conformation without the negative toxic effects associated with LPS. One of ordinary skill in the art would have been motivated to incorporate the protein taught by Brodeur into liposomes because doing so not only allows for the protein to obtain native-like conformation, but also has the added benefit of the inherent immunoadjuvant activity of the liposome vesicles. The secondary

Art Unit: 1645

references further teach that the liposomes may be used with or without a further adjuvant. Although the prior art references do not specifically recite that the liposome may be of bacterial cell origin, it was well known in the prior art that pharmaceutical compositions comprising liposomes could be constituted from phospholipids from bacterial cells, soybean or eggs and any one of these sources would work equally as well as obvious functional equivalents, absent evidence to the contrary.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references **individually** where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The prior art, taken as a whole, clearly provides motivation for combining/formulating a known Neisseria protein with a liposome of any origin, including one comprising a bacterial phospholipid from E.coli, N.menigitidis and N.lactamica.

It is noted that only instant claims 17 and 19 require the additional use of an adjuvant. The secondary references further teach that the liposomes may be used *with or without* a further adjuvant. Wright et al specifically teach that reactivity with native protein was considerably enhanced by incorporation of the adjuvant monophosporyl lipid A into the liposome.

The claims recite a known protein and argue that the novelty lies with the formulation of this known protein into a formulation with a liposome that comprises a bacterial phospholipid. Broduer teaches the identically claimed protein and the secondary references, e.g., Ward et al (Microbial Pathogenesis. 1996. 21: 499-512),

Art Unit: 1645

Idanpaan-Heikkila et al (Vaccine. 1995. 13(16): 1501-8), or Wright et al (Infection and Immunity, August 2002, 70(8): 4028-4034), teach that the incorporation of isolated *N.meningitidis* proteins into liposomes allows for the proteins to achieve optimal protein folding. It is taught that the use of liposomes replaced the use of LPS to promote native-like folding of the protein to an active conformation without the negative toxic effects associated with LPS. The use of adjuvants such as monophosphoryl lipid A or muramyl dipeptide along with the liposomes is specifically taught. However, it is taught that an effective bactericidal response was obtained with the purest preparation of protein incorporated into liposomes. Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to enhance the immune response of the NspA protein taught by Brodeur by incorporating into any liposome comprising a bacterial phospholipid, such as *E.coli*, *N.menigitidis* and *N.lactamica*, because the use of liposomes to achieve proper protein folding without the negative toxic effects associated with natively occurring LPS was well known in the *Neisseria* prior art at the time the invention was made.

3. Claims 1-5, 7, 11-27, 34 and 35 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Cadieux et al (Infect. Immun. Sept. 1999. 67(9): 4955-4959), Plante et al (Infect. Immun. June 1999. 67(6): 2855-2861) or Martin et al (J.Exp.Med. 1997. 185(7): 1173-1183) in view of anyone of Ward et al (Microbial Pathogenesis. 1996. 21: 499-512), Idanpaan-Heikkila et al (Vaccine. 1995. 13(16): 1501-8), or Wright et al (Infection and Immunity, August 2002, 70(8): 4028-4034).

Cadieux et al, Martin et al and Plante et al teach an isolated surface protein from *Neisseria meningitidis* which is 100% identical to the protein taught by Applicant's as SEQ ID NO: 2. Fragments of this protein are also taught as well as methods for producing it recombinantly. The references teach that the protein is highly conserved and is capable of protecting against meningococcal infections.

However, Cadieux et al, Martin et al and Plante et al do not specifically teach the use of a liposome, particularly one comprising a bacterial phospholipid, with their polypeptide.

Ward et al teach that the incorporation of isolated *N.meningitidis* proteins into liposomes allows for the proteins to achieve optimal protein folding. It is taught that the use of liposomes replaced the use of LPS to promote native-like folding of the protein to an active conformation without the negative toxic effects associated with LPS. The use of adjuvants such as monophosphoryl lipid A or muramyl dipeptide along with the liposomes is specifically taught. However, it is taught that an effective bactericidal response was obtained with the purest preparation of protein incorporated into liposomes. Page 503 teaches how to incorporate the proteins into liposomes. Liposomes composed of phosphatidylcholine and cholesterol are taught. Page 508 teaches that the advantage of using liposomes is primarily the potential for folding of the protein in the liposomal membrane to a native-like conformation and the inherent immunoadjuvant activity of the liposome vesicles.

Idanpana-Heikkila et al teach that when the outer membrane protein P1 from *N.meningitidis* was reconstituted with of phosphatidylcholine into liposomes, native

Art Unit: 1645

antigenic epitopes were formed. It is taught that the liposomes were reproducibly immunogenic at a low dose without any other adjuvant. The antibodies produced were both bactericidal and protective against infection in the infant rat model.

Wright et al teach the incorporation of the recombinant PorB outer membrane protein of *N.meningitidis* into liposomes for use as a vaccine. The liposome preparations proved to induce a much greater immune response than the PorB adsorbed to Al(OH)₃. It is further taught that reactivity with native protein was considerably enhanced by incorporation of the adjuvant monophosphoryl lipid A into the liposome. See abstract.

It would have been *prima facie* obvious to incorporate the isolated *N.meningitidis* protein taught by any one of Cadieux et al, Martin et al or Plante et al (which is the same as the protein taught by Applicant's as SEQ ID NO:2), into liposomes because the prior art, as evidenced by Ward, Idanpaan-Heikkila et al, and Wright, extensively taught that incorporating isolated, denatured or recombinant *N.meningitidis* proteins into liposomes allows for the proteins to achieve optimal protein folding which allowed for native-like conformation. It is taught that the use of liposomes replaced the use of LPS to promote native-like folding of the protein to an active conformation without the negative toxic effects associated with LPS. One of ordinary skill in the art would have been motivated to incorporate the protein taught by Cadieux et al, Martin et al and Plante et al into liposomes because doing so not only allows for the protein to obtain native-like conformation, but also has the added benefit of the inherent immunoadjuvant activity of the liposome vesicles. The secondary references further teach that the

Art Unit: 1645

liposomes may be used with or without a further adjuvant. The protein taught by Cadieux et al, Martin et al and Plante et al would inherently comprise an 'epitope-bearing portion'. The doses taught in instant claim 27 is consistent with what is taught by Brodeur et al. Although the prior art references do not specifically recite that the liposome may be of bacterial cell origin, it was well known in the prior art that pharmaceutical compositions comprising liposomes could be constituted from phospholipids from bacterial cells, soybean or eggs and any one of these sources would work equally as well as obvious functional equivalents. It is noted that the instant disclosure allows for the liposome to be synthesized or extracted from bacterial cells, soybeans or eggs. Phosphatidyl choline, phosphatidylserine, phosphatidylglycerol, glycerides, steroids, e.g., cholesterol are all suggested. The specific bacterial phospholipids which have been added to the claims would be expected to act functionally equivalent as these other sources of liposome. The specific bacterial phospholipids which have been added to the claims would be expected to act functionally equivalent as these other sources of liposome and the addition of the specific source of the bacterial phospholipid to the claims does not impart novelty.

The protein claimed and fragments thereof was very well known at the time the invention was made. Additionally, it was very well known that extensively teach that incorporating isolated, denatured or recombinant *N.meningitidis* proteins into liposomes allows for the proteins to achieve optimal protein folding which allowed for native-like conformation. It is taught that the use of liposomes replaced the use of LPS to promote native-like folding of the protein to an active conformation without the negative toxic

effects associated with LPS. One of ordinary skill in the art would have been motivated to incorporate the known NSA protein taught by Brodeur into liposomes, including those comprising a bacterial phospholipid, because doing so not only allows for the protein to obtain native-like conformation, but also has the added benefit of the inherent immunoadjuvant activity of the liposome vesicles.

Response to Applicants' Arguments:

Applicants argue that Plante, nor the combination of reference, teach a NspaA protein, variant or fragment thereof formulated with a liposome in a pharmaceutical composition. They argue that the prior art as a whole must suggest the desirability of making a the combination. This has been fully and carefully considered but is not deemed persuasive. First, the prior art as a whole does teach or suggest the desirability of formulating a Gram-negative bacterial protein with a liposome, synthetic or natural source. The term 'pharmaceutical composition' is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves

or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the prior art references recited above, e.g., Ward, Idanpaan-Heikkila et al, and Wright, extensively teach that incorporating isolated, denatured or recombinant *N.meningitidis* proteins into liposomes allows for the proteins to achieve optimal protein folding which allowed for native-like conformation. It is taught that the use of liposomes replaced the use of LPS to promote native-like folding of the protein to an active conformation without the negative toxic effects associated with LPS. One of ordinary skill in the art would have been motivated to incorporate the protein taught by Plante into liposomes because doing so not only allows for the protein to obtain native-like conformation, but also has the added benefit of the inherent immunoadjuvant activity of the liposome vesicles. The secondary references further teach that the liposomes may be used with or without a further adjuvant.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references **individually** where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The prior art, taken as a whole, clearly provides motivation for combining/formulating a known *Neisseria* protein with a liposome of any origin, including one comprising a bacterial phospholipid. It is noted that the instant disclosure allows for the liposome to be synthesized or extracted from bacterial cells, soybeans or eggs.

Art Unit: 1645

Phosphatidyl choline, phosphatiddylserine, phosphatidylglycerol, glycerides, steroids, e.g., cholesterol are all suggested. The specific bacterial phospholipids which have been added to the claims would be expected to act functionally equivalent as these other sources of liposome.

It is noted that only instant claims 17 and 19 require the additional use of an adjuvant. The secondary references further teach that the liposomes may be used *with or without* a further adjuvant. Wright et al specifically teach that reactivity with native protein was considerably enhanced by incorporation of the adjuvant monophosporyl lipid A into the liposome.

The protein claimed and fragments thereof was very well known at the time the invention was made. Additionally, it was very well known that extensively teach that incorporating isolated, denatured or recombinant *N.meningitidis* proteins into liposomes allows for the proteins to achieve optimal protein folding which allowed for native-like conformation. It is taught that the use of liposomes replaced the use of LPS to promote native-like folding of the protein to an active conformation without the negative toxic effects associated with LPS. One of ordinary skill in the art would have been motivated to incorporate the known NSA protein taught by Plante into liposomes, including those comprising a bacterial phospholipid, because doing so not only allows for the protein to obtain native-like conformation, but also has the added benefit of the inherent immunoadjuvant activity of the liposome vesicles.

The claims recite a well-known protein and argue that the novelty lies with the formulation of this well-known protein into a formulation with a liposome that comprises

a bacterial phospholipid. Plante, Cadieux et al, and Martin et al teach the identically claimed protein and the secondary references, e.g., Ward et al (*Microbial Pathogenesis*. 1996. 21: 499-512), Idanpana-Heikkila et al (*Vaccine*. 1995. 13(16): 1501-8), or Wright et al (*Infection and Immunity*, August 2002, 70(8): 4028-4034), teach that the incorporation of isolated *N.meningitidis* proteins into liposomes allows for the proteins to achieve optimal protein folding. It is taught that the use of liposomes replaced the use of LPS to promote native-like folding of the protein to an active conformation without the negative toxic effects associated with LPS. The use of adjuvants such as monophosphoryl lipid A or muramyl dipeptide along with the liposomes is specifically taught. However, it is taught that an effective bactericidal response was obtained with the purest preparation of protein incorporated into liposomes. Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to enhance the immune response of the NspA protein taught by any one of Plante, Cadieux et al, or Martin et al by incorporating into any liposome comprising a bacterial phospholipid, such as E.coli, *N.menigtidis* and *N.lactamica*, because the use of liposomes to achieve proper protein folding without the negative toxic effects associated with natively occurring LPS was well known in the *Neisseria* prior art at the time the invention was made.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

Application/Control Number: 10/650,123

Page 17

Art Unit: 1645

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

7/15/09